Remarks

Applicants hereby elect group II, claims 24-30 and claim 41; without prejudice to file

divisionals on the non-elected groups.

Applicant has amended claim 1 to specify that the binding polymer has a molecular

weight of about 7,000 to about 100,000. Support for this amendment may be found at page 5,

line 25. Support for new claim 42 may be found at page 5, lines 1-10.

Examiner has rejected claims 24-36 and 41 as anticipated by or obvious in view of

Thrakrar (US 6,337,040). Thrakrar neither discloses nor suggests binding polymers comprising

2-hydroxyethyl methacrylate and any specific molecular weight. Clearly, the claims as amended

are novel in view of Thrakrar.

The claims as amended are also patentable in view of Thrakrar. Attached herewith is a

Declaration of Douglas Vanderlaan showing that polyHEMA having a molecular weight greater

than the range recited in the present claims is not soluble in the solvents disclosed and used in

the Examples in Thrakrar. Thrakrar is silent as to the molecular weight of the binding polymer.

Clearly, the claims are patentable in view of Thrakrar.

Withdrawal of the rejections and allowance of the claims as amended is respectfully

requested.

Respectfully submitted,

Karen A. Harding

Reg. No. 33,967

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New Brunswick, NJ 08933

(904) 443-3074

Dated: July 16, 2004

- 8 -



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicants** 

: Frank Molock, et al.

Serial No.

: 10/027,579

Filed

: December 20, 2001

Title:

COLORANTS FOR USE IN TINTED CONTACT LENSES AND

METHODS FOR THEIR PRODUCTION

Art Unit

: 1732

Examiner

: Mathieu Vargot

Honorable Commissioner of Patents Alexandria, VA 22313

## **DECLARATION UNDER 37 CFR 1.132**

- I, Douglas Vanderlaan, PhD, declare as follows:
- 1.1 I am currently a Senior Scientist for Johnson & Johnson Vision Care, Inc. I received a Bachelor of Science in Chemistry from Calvin College, in 1979, and a Doctorate in Organic Chemistry from the Florida State University in 1984. I was a Research Fellow in the field of Organic Chemistry at the University of Michigan from 1984-1985. I was a Research Chemist at SWS Silicones from 1985-1986 and Senior Chemist at Reichhold Chemicals from 1986-1989. I have been a scientist for Johnson & Johnson Vision Care, Inc since 1989. In my tenure with Johnson & Johnson Vision Care, Inc. I have been engaged in research and study of materials for contact lenses
- 1.2 I reviewed the Examples of US 6,337,040 ("US `040") and tried to dissolve poly(2-hydroxyethylmethacrylate) (polyHEMA) in the solvents used in the Examples of US `040. No molecular weight was specified in US `040 for the binding polymers. The only molecular weight listed for polyHEMA in the 2000-2001 Aldrich Catalog was 300,000. A copy of page 1375 from the 2000-2001 Aldrich Catalog showing the polyHEMA entry is attached hereto.

- 1.3 I combined 2.0 g of poly(2-hydroxyethylmethacrylate) (300,000 M<sub>V</sub>, from Aldrich Chemicals) with 8.0 g 1-butanol and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.
- 1.4 I combined 3.0 g of poly(2-hydroxyethylmethacrylate) (300,000 M<sub>V</sub>, from Aldrich Chemicals) with 3.5 g 1-methoxy-2-propylacetate and 3.5 g cyclohexanone and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.
- 1.5 I combined 3.5 g of poly(2-hydroxyethylmethacrylate) (300,000  $M_V$ , from Aldrich Chemicals) with 3.25 g cyclohexanone and 3.25 g methyl ethyl ketone and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.
- 1.6 I combined 1.5 g of poly(2-hydroxyethylmethacrylate) (300,000  $M_V$ , from Aldrich Chemicals) with 8.5 g butoxy ethyl acetate and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.
- 1.7 None of the solvents used in the Examples of US `040 dissolved poly(HEMA) having a 300,000. Clearly US `040 did not appreciate the importance of molecular weight for binding polymers comprising poly(HEMA).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereof.

Inventor's Full Name

Douglas Vanderlaan, PhD

Signature

July 16, 2004

## BEST AVAILABLE COPY

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•				■ Pol	yhexy	lt 🔳
		\$ .		,		\$
( <b>ide) alcohol,</b>		15.90 43.00	44,570-3	Poly(3-hexylthiophene-2,5-diyl), regloregular [104934-50-1] mp 238°	1g	229.35
	٠ . مو			Solid. Greater than 98.5% head-to-tail regiospecific conformation. Average M <sub>w</sub> ca.	•	777
(ide) alcohol,		15.90		87,000 Product of Rieke® Metals, Inc.		
1 <sub>2</sub> (OCH <sub>2</sub> CH <sub>2</sub> ) <sub>2</sub> OPO <sub>3</sub> H <sub>2</sub>	25mL	43.00	51,082-3	Poly(3-hexylthiophene-2.5-diyl), regiorandom [104934-50-1]	1g	229.35
dda\	, _			For solid state properties see J. Am. Chem. Soc. 1994, 117, 233		
ide) monoalkylamide I8° d 1.700	5g 25g	15.90 43.00		Red solid. Conducting polymer. 1:1 (head-to-head):(head-to-tail) linkages of regioisomers	wi O	este (il suo G
44-3	,, -			regiolsomers Product of Rieke® Metals, Inc.	100g	20.00
:ide)	5mL 25mL	15.90 43.00	49,709-6 ©	Poly(4-hydroxybenzolc acid-co-ethylene terephthalate) [125300-07-4]	ioog	
:ide) monocarboxylic	5mL	15.90	43,234-2	Poly(4-hydroxybenzoic acid-co-6-hydroxy-2-naphthoic acid) [70679-92-4]	100g	21.10
3000 d 1.770 Fp none	- 25mL	43.00	The state of the s	(-OC <sub>6</sub> H <sub>4</sub> CO-) <sub>x</sub> (-OC <sub>10</sub> H <sub>6</sub> CO-) <sub>y</sub> mp 280° d 1.500 Liquid crystal random thermoplastic copolymer. Average M <sub>w</sub> >20,000. Reinforced with	500g	<del>-</del> 70.20
	•	7		ca. 15% glass fider		4444
			36,350-2	Poly(3-hydroxybutyric acid), natural origin [26063-00-3] [-COCH <sub>2</sub> CH(CH <sub>3</sub> )O-] <sub>n</sub>	10g 100g	265.40
<sub>2</sub> C(CH <sub>2</sub> ) <sub>4</sub> CO-] <sub>n</sub>	250g 1ka	19.30 53.70		R&S 1(2),3163D T <sub>m</sub> 172°C (DSC). Biodegradable polymer	. •	
14,200. Tm 55-65°		33.70	40 310-5	Poly/3-hydroxybutyric acid-co-3-hydroxyvaleric acid), natural origin	10g 100g	32.40 207.80
32° d 1.090	100mL 250mL	17.00		[80]81-31-3] [-COCH <sub>2</sub> CH(CH <sub>3</sub> )O-] <sub>X</sub> [-COCH <sub>2</sub> CH(C <sub>2</sub> H <sub>5</sub> )O-J <sub>y</sub> [a]B +4.5° (C=0.1, CHCl <sub>3</sub> )	luug	207.00
	ZOUNL	. 34.00		PHV content 5 wt %		
00 cps	400-	48.00		Produced via a controlled fermentation process using microorganisms. Biodegradable of the polymer		
?7° d 1.090	100g 250g	17.00 . 34.00	40,311-3	Poly/2 bydrovybybilo acid-co-3-bydrovygleric acid) natyral offgin	10g 100g	32.40 207.80
0-8,000 cps				[80181-31-3] [-COCH <sub>2</sub> CH(CH <sub>3</sub> )O-] <sub>x</sub> [-COCH <sub>2</sub> CH(C <sub>2</sub> H <sub>5</sub> )O-] <sub>y</sub> J-PHV content 8 wt. %	luug	207.80
d 1.140	, 100mL	17.70	1	Produced via a controlled fermentation process using microorganisms. Biodegradable		
IRYMATOR	250mL	32.10	40.010.1	polymer  Poly(3-hydroxybutyric acid-co-3-hydroxyvaleric acid), natural origin	10a	32.40
the Contraction of the Contracti	100mL	Î7.70	40,312-1		100g	207.80
1 .	250mL	32.10		PHV content 12 wt. %  Produced via a controlled fermentation process using microorganisms. Biodegradable	, <b>,</b>	• • •
***************************************		17.70		arcipólymer	ş ·	-ass 3;
lon 6/12 page 1240	250mL	32.10	<sup>06</sup> 19,206-6	Poly(2-hydroxyethyl methacrylate) [25249-16-5] [-CH <sub>2</sub> C(CH <sub>3</sub> )(CO <sub>2</sub> CH <sub>2</sub> CH <sub>2</sub> OH)-] <sub>n</sub>	1g 10g	13.20 57.00
i 6/9 page 1240				0.130 F-1-1(2), 11940 Fid. (2), 11071	250	113.80
1-8]	250mL	20.30	18,213-3	Poly(2-hydroxynropyl methacrylate) [25703-79-1]	1Òg	** <sup>2</sup> 66.40
5 1.5340 d 1.100			*	(-CH <sub>2</sub> C(CH <sub>3</sub> ) CO <sub>2</sub> CH <sub>2</sub> CH(OH)CH <sub>3</sub> ]-) <sub>n</sub> FT-IR 1(2),1190C Salety 2,2877A  R&S 1(2),3165K  Crystals  Ploly(A-hydroxystyrene) see Poly(4-vinylphenol)	209	134.20
10 page 1240			€ 1	Colyte-lightoxystylelic), socilolyte valyphonolog		
forms	100g	17.00	44 668-8	Poly(indene-co-coumarone) [35343-70-5] d 1.140 Fp >230°F(110°C)	1kg	18.50 41.40
190°C/2.16kg, DIN	250g	34.00	<b>新约</b>	Flake. Average M <sub>n</sub> <i>ca.</i> 735. 10 wt. % coumarone  Poly(Indene-co-coumarone) [35343-70-5]	. , ∃ka	18.50
ıtio 20:80. Tg -65°, Tm			<b>★</b>	Flake, Average M <sub>n</sub> ca. 1,090, 10 wt. % coumarone	ЗKG	, 41.40
114-14-6] mp 33°	250g	21.30	19,195-7	' Poly(isoborny) methacrylate) [64114-51-8] FT-IR 1(2),1194B R&S 1(2),316/⊑	10g	42.60
<i>?</i>	1kg	58.80	* ± 19145.5	Polylsobutylene [9003-27-4] [-CH <sub>2</sub> C(CH <sub>3</sub> ) <sub>2</sub> -] <sub>n</sub> nb 1.5045 d 0.920 FT-IR 1(2),1162B	100a	46.30
lity 2.0. Tm (DSC,			igr. 10,145-5	Safety 2 2878B R&S 1(2) 3151N RTECS# UD1010000	25Ug	80.70
alt-adipic acid] diol	250mL	20.50		Slab/chunk, Stabilized with 500 ppm 2,6-di- <i>tert</i> -butyl-4-methylphenol. Average M <sub>v</sub> ca. 420,000, M <sub>w</sub> ca. 500,000, M <sub>n</sub> ca. 200,000 (GPC/MALLS). Tg -76°. Tm 1.5°. Solubility	Ç., G	
(110°C) onality 2.1	1L	56.50		parameter 7.7		
1 <sub>2</sub> ) <sub>5</sub> CH <sub>3</sub> ]-) <sub>n</sub> n <sup>®</sup> 1.4810 1ABLE LIQUID TOXIC Average M <sub>w</sub> ca.	25g	101.90	07 18,146-3 *	B Polyisobutylene [9003-27-4] [-CH <sub>2</sub> C(CH <sub>3</sub> ) <sub>2</sub> -] <sub>n</sub>	100g 250g	
- "				CH₃ CH₃	]	
,(CH <sub>2</sub> ) <sub>4</sub> CH <sub>2</sub> -					СН3	
CH <sub>3</sub>				$(\downarrow,\downarrow)$ $(\downarrow,\downarrow)$ $(\downarrow,\downarrow)$	<u>,                                    </u>	
ж <sub>2</sub> -¢-сн <sub>2</sub> -				$\left(\frac{1}{1-1}\right)\left(\frac{1}{1-1}\right)$	7	
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44,570-3

44,668-8

...19,195-7